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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/356,322	11/24/1998	TIDHAR DARI SHALON	STFD:009--1	7679

7590 03/30/2004

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action**Application No.**

09/356,322

Applicant(s)

SHALON ET AL.

Examiner

Ardin Marschel

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached explanation.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: of reasons of record as further explained as attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 7-40.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

DETAILED ACTION

Further Explanation of item # 2(a) on the attached Advisory Action:

The proposed amendment, filed 1/29/04, is denied entry due to being in improper amendment form. Specifically all previously pending claims have not been indicated thereon regarding status, such as claims 1-6. This improper amendment form is a new issue requiring further consideration and/or search.

Further Explanation of item # 5 on the attached Advisory Action:

The NEW MATTER rejection directed to claims 34, 35, and 39 is maintained and reiterated from the previous office action, mailed 9/30/03, due to the above indicated non-entry of the amendment thus leaving the NEW MATTER still present in the claims. The only argument of applicants regarding this issue is the amending which has not been entered and therefore is moot.

The rejection under 35 U.S.C. § 103(a) of claims 7-40 based on Pirrung et al. (WO 90/15070) is maintained and reiterated from the previous office action, mailed 9/30/03. Applicants argue that the reference does not teach or suggest a microarray of DNA sequences which are at least 50 subunits in length, individually applied to each region in the microarray and directly deposited on the surface of the substrate. In response. The deposition of such lengthy sequences on the microarray surface was already pointed to in the previous office action, mailed 10/1/02. The probe microarrays therein summarized in the reference is directed to specific sequence probes on the array whereupon sample nucleic acids that are lengthy, that is, over 50 subunits in length, are deposited on the microarray surface via hybridization to covalently attached probes. This type of microarray assemblage supplies a prima facie case for this rejection. Applicants have not negated this supporting description in the reference, but rather merely alleged a difference without arguing the specific basis for the rejection.

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Such an argument is therefore not directed to the basis for the rejection and therefore non-persuasive. Additionally, the instant claims are drawn to a substrate which is a microarray which is deemed a composition of matter, or possibly, an apparatus. The individual application of DNA sequences onto an array substrate surface as in the instant claims is a process limitation regarding how the claimed microarray is made. If another process results in the same array apparatus or composition of matter, it is a proper reference supporting a rejection such as this. In this case the lengthy, over 50 subunit, DNA sequences are immobilized on the array surface by the combination of a covalent probe attachment followed by hybridization of sample DNA polynucleotide sequences. This results in specific immobilization via sequence complementarity specificity of the probes on the surface which thus results in individual sequences immobilized on the array surfaces identical in compositions as instantly claimed. Therefore this argument is non-persuasive as the process limitations in the instant claims do not distinguish the instant invention over the cited prior art. Applicants then argue that there is no disclosure in Pirrung et al. regarding nucleic acid immobilization at 400 or more discrete regions per square centimeter, but only speculation, thus making the reference non-enabling. In response the immobilization of nucleic acids, such as DNA onto a surface is old in the art and therefore disclosure of such methodology is not required beyond the disclosure of such probe immobilization onto a substrate surface to be enabling. Thus, the reference is deemed enabling on this issue. Applicants have neither argued nor responded to the issue of this DNA immobilization being old in the art and therefore have not responded to a critical aspect of the basis of this rejection. This argument therefore is non-persuasive. Additionally, densities of discrete probe or discrete regions well within the 400 or more probes or regions per square centimeter was pointed to in the previous office action, mailed 10/1/02, and not argued by

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applicants. This aspect of applicants' argument is therefore also non-persuasive as not being directed to the basis for the rejection. Applicants then argue that short probes on a substrate as attached in Pirrung et al. cannot be as specific as the sequences as instantly claimed. In response the rejection is based on immobilization of longer polynucleotide DNA sequences via hybridization. Therefore, such long sequences will have the same specificity as such embodiments as instantly claimed. Therefore, this does not distinguish the invention as arguing embodiments which are also claimed. Lastly applicants argue that the Pirrung et al. microarrays will be cross-contaminated as a result of preparation methodology which is imperfect regarding masking. In response the characteristic of cross-contamination is not limited in most of the instant claims and is NEW MATTER in instant claims that do have such a limitation. Even if this limitation was not considered NEW MATTER it would not distinguish the instant invention over that of the reference because there is no specific difference between what cross contamination or lack thereof exists in the instantly claimed invention. Also, one reasonable interpretation is that both the instantly claimed invention as well as that of Pirrung et al. are directed to microarrays wherein the hybridization, via complementarity, of nucleic acids results in differential identification from one region on such arrays to another and yet another etc. over the entire surface of the array. Thus, the level of cross-contamination in both invention descriptions must be low enough or essentially free enough in order to result in such region by region specific sequence differentiation. This is reasonably interpreted as being "essentially free of cross contamination" as instantly claimed as well as regarding the arrays described in the reference. Thus, in summary, applicants' arguments are non-persuasive.

No claim is allowed.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

March 26, 2004


ARDIN H. MARSCHEL 3/26/04
PRIMARY EXAMINER